

AMENDED IN SENATE JUNE 15, 2014

AMENDED IN ASSEMBLY MAY 15, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 1727

Introduced by Assembly Member Rodriguez

February 14, 2014

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1727, as amended, Rodriguez. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy that is owned by, or contracts with, the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards is eligible for donation to the repository and distribution program. Existing law also prohibits the donation of controlled substances to the repository and distribution program.

This bill would also prohibit the donation to a county repository and distribution program of a medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy that ~~restricts~~ *prohibits* that inventory transfer *or requires the inventory transfer to receive prior authorization from the manufacturer of the medication.*

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 150204 of the Health and Safety Code
2 is amended to read:
3 150204. (a) (1) A county may establish, by an action of the
4 county board of supervisors or by an action of the public health
5 officer of the county, as directed by the county board of
6 supervisors, a repository and distribution program for purposes of
7 this division. The county shall advise the California State Board
8 of Pharmacy within 30 days from the date it establishes a repository
9 and distribution program.
10 (2) Only an eligible entity, pursuant to subdivision (a) of Section
11 150201, may participate in this program to dispense medication
12 donated to the drug repository and distribution program.
13 (3) An eligible entity that seeks to participate in the program
14 shall inform the county health department and the California State
15 Board of Pharmacy in writing of its intent to participate in the
16 program. An eligible entity may not participate in the program
17 until it has received written or electronic documentation from the
18 county health department confirming that the department has
19 received its notice of intent.
20 (4) (A) A participating entity shall disclose to the county health
21 department on a quarterly basis the name and location of the source
22 of all donated medication it receives.
23 (B) A participating primary care clinic, as described in paragraph
24 (3) of subdivision (a) of Section 150201 shall disclose to the county
25 health department the name of the licensed physician who shall
26 be accountable to the California State Board of Pharmacy for the
27 clinic's program operations pursuant to this division. This physician
28 shall be the professional director, as defined in subdivision (c) of
29 Section 4182 of the Business and Professions Code.
30 (C) The county board of supervisors or public health officer of
31 the county shall, upon request, make available to the California
32 State Board of Pharmacy the information in this division.
33 (5) The county board of supervisors, the public health officer
34 of the county, and the California State Board of Pharmacy may
35 prohibit an eligible or participating entity from participating in the

1 program if the entity does not comply with the provisions of the
2 program, pursuant to this division. If the county board of
3 supervisors, the public health officer of the county, or the California
4 State Board of Pharmacy prohibits an eligible or participating
5 entity from participating in the program, it shall provide written
6 notice to the prohibited entity within 15 days of making this
7 determination. The county board of supervisors, the public health
8 officer of the county, and the California State Board of Pharmacy
9 shall ensure that this notice also is provided to one another.

10 (b) A county that elects to establish a repository and distribution
11 program pursuant to this division shall establish written procedures
12 for, at a minimum, all of the following:

13 (1) Establishing eligibility for medically indigent patients who
14 may participate in the program.

15 (2) Ensuring that patients eligible for the program shall not be
16 charged for any medications provided under the program.

17 (3) Developing a formulary of medications appropriate for the
18 repository and distribution program.

19 (4) Ensuring proper safety and management of any medications
20 collected by and maintained under the authority of a participating
21 entity.

22 (5) Ensuring the privacy of individuals for whom the medication
23 was originally prescribed.

24 (c) Any medication donated to the repository and distribution
25 program shall comply with the requirements specified in this
26 division. Medication donated to the repository and distribution
27 program shall meet all of the following criteria:

28 (1) The medication shall not be a controlled substance.

29 (2) The medication shall not have been adulterated, misbranded,
30 or stored under conditions contrary to standards set by the United
31 States Pharmacopoeia (USP) or the product manufacturer.

32 (3) The medication shall not have been in the possession of a
33 patient or any individual member of the public, and in the case of
34 medications donated by a health or care facility, as described in
35 Section 150202, shall have been under the control of a staff
36 member of the health or care facility who is licensed in California
37 as a health care professional or has completed, at a minimum, the
38 training requirements specified in Section 1569.69.

39 (d) (1) Only medication that is donated in unopened,
40 tamper-evident packaging or modified unit dose containers that

1 meet USP standards is eligible for donation to the repository and
2 distribution program, provided lot numbers and expiration dates
3 are affixed. Medication donated in opened containers shall not be
4 dispensed by the repository and distribution program, and once
5 identified, shall be quarantined immediately and handled and
6 disposed of in accordance with the Medical Waste Management
7 Act (Part 14 (commencing with Section 117600) of Division 104).

8 (2) (A) A medication that is the subject of a United States Food
9 and Drug Administration managed risk evaluation and mitigation
10 strategy pursuant to Section 355-1 of Title 21 of the United States
11 Code ~~may shall not~~ be donated ~~only~~ if this inventory transfer is
12 ~~not restricted prohibited~~ by that strategy, ~~and or if the inventory~~
13 ~~transfer requires prior authorization from the manufacturer of the~~
14 ~~medication.~~

15 (B) *A medication that is the subject of a United States Food and*
16 *Drug Administration managed risk evaluation and mitigation*
17 *strategy pursuant to Section 355-1 of Title 21 of the United States*
18 *Code, the donation of which is not prohibited pursuant to*
19 *subparagraph (A), shall be managed and dispensed according to*
20 *the requirements of that strategy.*

21 (e) A pharmacist or physician at a participating entity shall use
22 his or her professional judgment in determining whether donated
23 medication meets the standards of this division before accepting
24 or dispensing any medication under the repository and distribution
25 program.

26 (f) A pharmacist or physician shall adhere to standard pharmacy
27 practices, as required by state and federal law, when dispensing
28 all medications.

29 (g) Medication that is donated to the repository and distribution
30 program shall be handled in the following ways:

31 (1) Dispensed to an eligible patient.

32 (2) Destroyed.

33 (3) Returned to a reverse distributor or licensed waste hauler.

34 (4) (A) Transferred to another participating entity within the
35 county to be dispensed to eligible patients pursuant to this division.
36 Notwithstanding this paragraph, a participating county-owned
37 pharmacy may transfer eligible donated medication to a
38 participating county-owned pharmacy within another adjacent
39 county that has adopted a program pursuant to this division, if the
40 pharmacies transferring the medication have a written agreement

1 between the entities that outlines protocols and procedures for safe
2 and appropriate drug transfer that are consistent with this division.

3 (B) Medication donated under this division shall not be
4 transferred by any participating entity more than once, and after
5 it has been transferred, shall be dispensed to an eligible patient,
6 destroyed, or returned to a reverse distributor or licensed waste
7 hauler.

8 (C) Medication transferred pursuant to this paragraph shall be
9 transferred with documentation that identifies the drug name,
10 strength, and quantity of the medication, and the donation facility
11 from where the medication originated shall be identified on
12 medication packaging or in accompanying documentation. The
13 document shall include a statement that the medication may not
14 be transferred to another participating entity and must be handled
15 pursuant to subparagraph (B). A copy of this document shall be
16 kept by the participating entity transferring the medication and the
17 participating entity receiving the medication.

18 (h) Medication that is donated to the repository and distribution
19 program that does not meet the requirements of this division shall
20 not be distributed or transferred under this program and shall be
21 either destroyed or returned to a reverse distributor. This
22 medication shall not be sold, dispensed, or otherwise transferred
23 to any other entity.

24 (i) Medication donated to the repository and distribution program
25 shall be maintained in the donated packaging units until dispensed
26 to an eligible patient under this program, who presents a valid
27 prescription. When dispensed to an eligible patient under this
28 program, the medication shall be in a new and properly labeled
29 container, specific to the eligible patient and ensuring the privacy
30 of the individuals for whom the medication was initially dispensed.
31 Expired medication shall not be dispensed.

32 (j) Medication donated to the repository and distribution program
33 shall be segregated from the participating entity's other drug stock
34 by physical means, for purposes including, but not limited to,
35 inventory, accounting, and inspection.

36 (k) A participating entity shall keep complete records of the
37 acquisition and disposition of medication donated to, and
38 transferred, dispensed, and destroyed under, the repository and
39 distribution program. These records shall be kept separate from
40 the participating entity's other acquisition and disposition records

1 and shall conform to the Pharmacy Law (Chapter 9 (commencing
2 with Section 4000) of Division 2 of the Business and Professions
3 Code), including being readily retrievable.

4 (l) Local and county protocols established pursuant to this
5 division shall conform to the Pharmacy Law regarding packaging,
6 transporting, storing, and dispensing all medications.

7 (m) County protocols established for packaging, transporting,
8 storing, and dispensing medications that require refrigeration,
9 including, but not limited to, any biological product as defined in
10 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
11 an intravenously injected drug, or an infused drug, shall include
12 specific procedures to ensure that these medications are packaged,
13 transported, stored, and dispensed at appropriate temperatures and
14 in accordance with USP standards and the Pharmacy Law.

15 (n) Notwithstanding any other provision of law, a participating
16 entity shall follow the same procedural drug pedigree requirements
17 for donated drugs as it would follow for drugs purchased from a
18 wholesaler or directly from a drug manufacturer.